

AMENDMENTS TO THE CLAIMS:

After entry of the Amendments to the Claims presented in the Amendment After Final Rejection filed on November 13, 2007, please further amend the claims as follows:

1. (Currently Amended) A hydrostatic delivery system, comprising a core consisting of a homogeneous mixture comprising [[of]]:

a) a hydrostatic couple comprising:

- i) one, or more than one hydrodynamic fluid-imbibing polymer comprising one, or more than one acrylic-acid polymer cross-linked with allylsucrose or allylpentaerythritol; and
- ii) one, or more than one hydrostatic pressure-modulating agent comprising one, or more than one homopolymer of a cross-linked polyvinylpyrrolidone; and

b) an agent of interest,

wherein said core of said hydrostatic delivery system is provided in a dosage form selected from the group consisting of a solid compact, an extrusion spheroid, and a capsule filled with a blend selected from the group consisting of a granulated blend, a particulate blend, a spheroidal blend, a compact blend, and a dry blend

~~wherein said agent of interest is released in a controlled manner with a zero-order or near zero-order release kinetics over a therapeutically practical time period following administration of said hydrostatic delivery system.~~

2. (Cancelled)

3. (Previously Presented) The hydrostatic delivery system of claim 1, wherein said one, or more than one hydrodynamic fluid-imbibing polymer is a cross-linked polymer having a swell capacity in a fluid environment of between about 1 weight % to about 3000 weight %.

4. (Original) The hydrostatic delivery system according to claim 3, wherein said cross-linked polymer is present from about 4 weight % to about 96 weight % of the total formulation.
5. (Previously Presented) The hydrostatic delivery system according to claim 1, wherein said one, or more than one hydrostatic pressure modulating agent is a cross-linked, rapidly swelling polymer having a swell capacity in a fluid environment of between about 0.5 weight % to about 500 weight %.
6. (Previously Presented) The hydrostatic delivery system according to claim 5, wherein said cross-linked rapidly swelling polymer is present from about 0.5 weight % to about 50 weight % of the total formulation.
7. (Previously Presented) The hydrostatic delivery system according to claim 1, wherein said one, or more than one hydrostatic pressure modulating agent further comprises an expansion source.
8. (Original) The hydrostatic delivery system according to claim 7, wherein said expansion source is selected from the group consisting of a carbon-dioxide precursor, an oxygen precursor, and a chlorine dioxide precursor.
9. (Cancelled)
10. (Previously Presented) The hydrostatic delivery system according to claim 3, wherein:
said one, or more than one hydrostatic pressure modulating agent further comprises an expansion source selected from the group consisting of a carbon dioxide precursor, an oxygen precursor and a chlorine dioxide precursor.
11. (Previously Presented) The hydrostatic delivery system according to claim 1 wherein the agent of interest comprises a plurality of discrete active particulates.

12. (Currently Amended) The hydrostatic delivery system according to claim [[40]] 43, wherein:

said one, or more than one hydrodynamic fluid-imbibing polymer comprises one or more of the compounds selected from the group consisting of:

- i) an acrylic-acid polymer cross-linked with allylsucrose or allylpentaerythritol;
- ii) one or more starch derivatives cross-linked by epichlorhydrin, phosphorous oxychloride (POCl₃), or sodium trimetaphosphate;
- iii) a crosslinked polyglucan;
- iv) a crosslinked polyethylenimine;
- v) a crosslinked polyallylamine, and
a combination thereof, and

wherein said one, or more than one hydrostatic pressure modulating agent comprises one or more of the compounds selected from the group consisting of:

- a) a homopolymer of cross-linked N-vinyl-2-pyrrolidone;
- b) a rapidly expanding cross-linked cellulose derivative; and
a combination thereof.

13. (Cancelled)

14. (Currently Amended) The hydrostatic delivery system according to claim [[40]] 43, wherein said one, or more than one hydrodynamic fluid-imbibing polymer is an acrylic-acid polymer cross-linked with allylsucrose or allylpentaerythritol.

15. (Previously Presented) The hydrostatic delivery system according to claim 1, wherein said acrylic-acid polymer has a viscosity from about 3,000 centipoise to about 45,000 centipoise at 0.5% w/w concentration in water at 25°C.

16. (Original) The hydrostatic delivery system according to claim 15, wherein said acrylic-acid polymer has a primary particle size range from about 3.00 to about 10.00 microns in diameter.

17. (Currently Amended) The hydrostatic delivery system according to claim ~~[[40]]~~ 43, wherein said one, or more than one hydrodynamic fluid imbibing polymer is a polyglucan selected from the group consisting of amylose, dextran, pullulan succinate containing diester or diether crosslinks, pullulan glutarates containing diester or diether crosslinks, and a combination thereof.
18. (Currently Amended) The hydrostatic delivery system according to claim ~~[[40]]~~ 43, wherein said one, or more than one hydrostatic pressure modulating agent comprises a homopolymer of cross-linked N-vinyl-2-pyrrolidone.
19. (Previously Presented) The hydrostatic delivery system according to claim 1, wherein each of said one, or more than one homopolymer of a cross-linked N-vinyl-2-pyrrolidone has a particle size from about 9 microns to about 150 microns.
20. (Currently Amended) The hydrostatic delivery system according to claim ~~[[40]]~~ 43, wherein said one, or more than one hydrostatic pressure modulating agent is a rapidly expanding cross-linked cellulose derivative selected from the group consisting of cross-linked carboxymethyl cellulose, sodium starch glycolate, and a combination thereof.
21. (Previously Presented) The hydrostatic delivery system according to claim 8, wherein said carbon dioxide precursor is selected from the group consisting of carbonates, sesquicarbonate, hydrogen carbonate, potassium carbonate, lithium carbonate, sodium carbonate, ammonium carbonate, sodium amino acid carbonate, sodium glycine carbonate, L-lysine carbonate and arginine carbonate.
22. (Original) The hydrostatic delivery system according to claim 8, wherein said oxygen precursor is selected from the group consisting of sodium percarbonate, sodium perborate monohydrate, anhydrous sodium perborate, effervescent perborate, and sodium dichloroisocyanurate.

23. (Original) The hydrostatic delivery system according to claim 8, wherein said chlorine dioxide precursor is selected from the group consisting of sodium hypochlorite and calcium hypochlorite.

24. (Currently Amended) The hydrostatic delivery system according to claim 1, wherein said core of said hydrostatic delivery system is in the form of a multiparticulate matrix tablet, or is filled into a capsule.

25. (Previously Presented) The hydrostatic delivery system according to claim 1, further comprising an enteric coating or one or more pH sensitive barrier polymers.

26. (Previously Presented) The hydrostatic delivery system according to claim 1, wherein the agent of interest is selected from the group consisting of analgesic, anti-inflammatory, antimicrobial, amoebicidal, trichomonocidal agents, anti-Parkinson, anti-malarial, anticonvulsant, anti-depressants, antiarthritics, anti-fungal, antihypertensive, antipyretic, anti-parasite, antihistamine, alpha-adrenergic agonist, alpha blocker, anesthetic, bronchial dilator, biocide, bactericide, bacteriostat, beta adrenergic blocker, calcium channel blocker, cardiovascular drug, contraceptive, decongestants, diuretic, depressant, diagnostic, electrolyte, hypnotic, hormone, hyperglycemic, muscle relaxant, muscle contractant, ophthalmic, parasympathomimetic, psychic energizer, sedative, sympathomimetic, tranquilizer, urinary, vaginal, viricide, vitamin, non-steroidal anti-inflammatory, angiotensin converting enzyme inhibitors, polypeptide, proteins, and sleep inducers.

27. (Previously Presented) The hydrostatic delivery system of claim 1, further comprising one or more pharmaceutical excipients selected from the group consisting of a viscosity enhancer, and enteric polymer, a pH-specific barrier polymer, a diluent, an anti-adherent, a glidant, a binder, a solubilizer, a channeling agent, a wetting agent, a buffering agent, a flavorant, an adsorbent, a sweetening agent, a colorant and a lubricant.

28. (Previously Presented) The hydrostatic delivery system of claim 1, further comprising an adjuvant.

29. (Currently Amended) The hydrostatic delivery system of claim 1, wherein said core of said hydrostatic delivery system is in the form of a matrix solid compact, made by a compression or pelletization method.

30. (Currently Amended) The hydrostatic delivery system of claim 1, wherein said core of said hydrostatic delivery system is in the form of a matrix extrusion spheroid, made by a wet or dry extrusion method.

31. (Currently Amended) The hydrostatic delivery system of claim 1, wherein said core of said hydrostatic delivery system is produced from granulated or microencapsulated ~~to form~~ particulates that ~~may be~~ are compressed into a solid compact ~~compact~~ or filled into a capsule ~~capsule~~.

32. (Currently Amended) The hydrostatic delivery system of claim 1, wherein said core of said hydrostatic delivery system is in the form of a granulated blend, a particulate blend, a spheroidal blend, a compact blend, or a dry blend, and ~~wherein said hydrostatic delivery system is fillable~~ filled into a capsule ~~or is suspended in a suitable liquid vehicle~~.

33. (Cancelled)

34. (Currently Amended) The hydrostatic delivery system according to claim ~~[[40]]~~ 43, wherein said one, or more than one hydrodynamic fluid-imbibing polymer comprises one or more of the compounds selected from the group consisting of:

- i) an acrylic-acid polymer cross-linked with allylsucrose or allylpentaerythritol;
 - ii) one or more starch derivatives cross-linked by epichlorhydrin, phosphorous oxychloride (POCl₃), or sodium trimetaphosphate;
 - iii) a crosslinked polyglucan;
 - iv) a crosslinked polyethylenimine;
 - v) a crosslinked polyallylamine, and
- a combination thereof.

35. (Currently Amended) The hydrostatic delivery system according to claim [[40]] 43, wherein said one, or more than one hydrostatic pressure modulating agent comprises one or more of the compounds selected from the group consisting of:

- a) a homopolymer of cross-linked N-vinyl-2-pyrrolidone;
 - b) a rapidly expanding cross-linked cellulose derivative; and
- a combination thereof.

36. (Cancelled)

37. (Currently Amended) A hydrostatic delivery system, comprising a core consisting of a homogeneous mixture comprising [[of]]:

- a) an agent of interest; and
- b) a hydrostatic couple, comprising:
 - i) one, or more than one cross-linked hydrodynamic fluid-imbibing polymer comprising one, or more than one compound selected from the group consisting of amylose containing diester or diether crosslinks, dextran containing diester or diether crosslinks, pullulan succinate containing diester or diether crosslinks, pullulan glutarates containing diester or diether crosslinks, and a combination thereof; and
 - ii) one, or more than one cross-linked hydrostatic pressure modulating agent,

~~wherein said agent of interest is released in a controlled manner with zero-order or near-zero-order release kinetics following administration of the hydrostatic delivery system~~
wherein said core of said hydrostatic delivery system is provided in a dosage form selected from the group consisting of a solid compact, an extrusion spheroid, and a capsule filled with a blend selected from the group consisting of a granulated blend, a particulate blend, a spheroidal blend, a compact blend, and a dry blend.

38. (Currently Amended) A hydrostatic delivery system, comprising a core consisting of a homogeneous mixture comprising [[of]]:

- a) an agent of interest;

- b) a hydrostatic couple, comprising:
 - i) one, or more than one cross-linked hydrodynamic fluid-imbibing polymer; and
 - ii) one, or more than one cross-linked hydrostatic pressure modulating agent; and
- c) an expansion source comprising an oxygen precursor selected from the group consisting of sodium percarbonate, sodium perborate monohydrate, anhydrous sodium perborate, effervescent perborate and sodium dichloroisocyanurate,

wherein:

said core of said hydrostatic delivery system is ~~in the form of a solid compact~~ provided in a dosage form selected from the group consisting of a solid compact, an extrusion spheroid, and a capsule filled with a blend selected from the group consisting of a granulated blend, a particulate blend, a spheroidal blend, a compact blend, and a dry blend, and

said agent of interest is released in a controlled manner with zero-order or near zero-order release kinetics when the hydrostatic delivery system comes into contact with an external fluid.

39. (Currently Amended) A hydrostatic delivery system, comprising a core consisting of a homogeneous mixture comprising ~~[[of]]~~:

- a) an agent of interest;
- b) a hydrostatic couple, comprising:
 - i) one, or more than one cross-linked hydrodynamic fluid-imbibing polymer; and
 - ii) one, or more than one cross-linked hydrostatic pressure modulating agent; and
- c) an expansion source comprising a chlorine dioxide precursor selected from the group consisting of sodium hypochlorite and calcium hypochlorite,

wherein:

said core of said hydrostatic delivery system is ~~in the form of a solid compact~~ provided in a dosage form selected from the group consisting of a solid compact, an extrusion spheroid,

and a capsule filled with a blend selected from the group consisting of a granulated blend, a particulate blend, a spheroidal blend, a compact blend, and a dry blend, and

said agent of interest is released in a controlled manner with zero-order or near zero-order release kinetics when the hydrostatic delivery system comes into contact with an external fluid.

40. (Currently Amended) A hydrostatic delivery system, comprising ~~a homogeneous mixture of:~~

I) a core consisting of ~~homogeneous~~ a homogeneous mixture of comprising:

- a) an agent of interest; and
- b) a hydrostatic couple, comprising:
 - i) one, or more than one cross-linked hydrodynamic fluid-imbibing polymer; and
 - ii) one, or more than one cross-linked hydrostatic pressure modulating agent; and

II) wherein said hydrostatic delivery system is at least partially surrounded by an enteric coating containing one, or more than one pH sensitive barrier polymer,

wherein said core of said hydrostatic delivery system is provided in a dosage form selected from the group consisting of a solid compact, an extrusion spheroid, and a capsule filled with a blend selected from the group consisting of a granulated blend, a particulate blend, a spheroidal blend, a compact blend, and a dry blend, and

wherein said agent of interest is released in a controlled manner with zero-order or near zero-order release kinetics over a therapeutically practical time period following administration of said hydrostatic delivery system.

41. (Currently Amended) A hydrostatic delivery system, comprising a core consisting of a homogeneous mixture comprising [[of]]:

- a) an agent of interest;
- b) a hydrostatic couple, comprising:
 - i) one, or more than one cross-linked hydrodynamic fluid-imbibing polymer; and

- ii) one, or more than one cross-linked hydrostatic pressure modulating agent, wherein:

said core of said hydrostatic delivery system is in the form of a matrix extrusion spheroid; and

said agent of interest is released in a controlled manner with zero-order or near zero-order release kinetics over a therapeutically practical time period following administration of said hydrostatic delivery system.

42. (Previously Presented) The hydrostatic delivery system according to claim 1, wherein:

the weight ratio of said one, or more than one hydrodynamic fluid-imbibing polymer to said one, or more than one hydrostatic pressure modulating agent is from about 35:1 to about 167:1; and

the weight ratio of said one, or more than one hydrodynamic fluid-imbibing polymer to said agent of interest is from about 1:1 to about 9:1.

43. (New) A hydrostatic delivery system, comprising:

a core consisting of a homogeneous mixture comprising:

- a) an agent of interest; and
- b) a hydrostatic couple, comprising:
 - i) one, or more than one cross-linked hydrodynamic fluid-imbibing polymer; and
 - ii) one, or more than one cross-linked hydrostatic pressure modulating agent;

wherein said core of said hydrostatic delivery system is provided in a dosage form selected from the group consisting of a solid compact, an extrusion spheroid, and a capsule filled with a blend selected from the group consisting of a granulated blend, a particulate blend, a spheroidal blend, a compact blend, and a dry blend.

44. (New) The hydrostatic delivery system of claim 1, wherein said agent of interest is released in a controlled manner with zero-order or near zero-order release kinetics over a

therapeutically practical time period following administration of said hydrostatic delivery system.

45. (New) The hydrostatic delivery system of claim 37, wherein said agent of interest is released in a controlled manner with zero-order or near zero-order release kinetics over a therapeutically practical time period following administration of the hydrostatic delivery system.

46. (New) The hydrostatic delivery system of claim 43, wherein said agent of interest is released in a controlled manner with zero-order or near zero-order release kinetics over a therapeutically practical time period following administration of said hydrostatic delivery system.